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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,851	03/23/2005	Philip C. Roy	2870(203-3505)	6326
50855	7590	09/05/2007		
COVIDIEN 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473			EXAMINER TRUONG, THANH K	
			ART UNIT	PAPER NUMBER
			3721	
			MAIL DATE	DELIVERY MODE
			09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,851	Applicant(s) ROY, PHILIP C.	
	Examiner Thanh K. Truong	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2007 has been entered.
2. Applicant's cancellation of claims 3, 4 and 19 is acknowledged.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Mizzy et al. (3,859,996).

Viola et al. discloses an apparatus comprising:

a housing having a fixed handle (20) - It is construed that **the housing** in Viola et al. comprises the frame portions that cover all components of the apparatus (10) – see figure 1;

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a clamping handle (44) mounted to the housing and selectively movable relative to the fixed handle from a first position in spaced relation relative to the fixed handle to a second position closer to the fixed handle to actuate the clamping of tissue;

an adapter yoke (76) which translates within the housing upon actuation of the clamping handle, the adapter yoke mechanically cooperating with a lead screw (78) disposed within the housing to actuate the tool assembly to clamp tissue;

a drive assembly (22) disposed within the housing, the drive assembly including a shaft (42), the shaft being mechanically engaged with the lead screw (78) disposed within the housing such that upon selective activation of the drive assembly, the shaft rotates said lead screw to advance a roll nut (94) distally along the lead screw to force a firing piston into a tool assembly when mounted on the housing to deform the surgical fasteners through and fastening the tissue (figures 9 & 10).

Viola et al. discloses the claimed invention, but it does not expressly disclose that the drive assembly is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger.

Mizzy et al. discloses an apparatus that comprises a pressure sensitive trigger mechanism (abstract) that provides a means to effectively controlling the drive assembly.

Mizzy et al. demonstrates that it is old and well known in the art to use the pressure sensitive trigger to activate and regulate the drive assembly of an apparatus so that drive assembly is selectively variable to regulate the speed at which the surgical

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fasteners are deformed, and the stapler comprises a pressure sensitive trigger to provide a more accurately control of the stapler device.

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al. apparatus by incorporating the pressure sensitive trigger mechanism as taught by Mizzy et al. so that it comprises the drive assembly that is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger mechanism to provide a more responsive and more precise surgical instrument.

Regarding claims 8 and 9, the modified Viola et al. by Mizzy et al. further discloses: wherein the stapler includes a switch for reversing the rotation of the shaft of the drive assembly upon activation thereof (Viola et al. - column 5, lines 7-12), and the shaft (42) rotates upon activation of the drive assembly (22), which in turn rotates the lead screw (78).

5. Claims 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Mizzy et al. (3,859,996) and further in view of Green et al. (US 2002/0096550).

As discussed above in paragraph 4 of this office action, the modified Viola et al. discloses the claimed invention, but does not expressly disclose that: the drive assembly is pneumatic powered, the safety mechanism as describe in claims 5 and 7.

It is old and well known in the art to employ a pneumatic drive assembly in place of electrical or hydraulic drive assembly and it is also well known to have a safety mechanism in a surgical stapler to prevent accidental triggering of the device.

Green et al. discloses a surgical stapler that comprising: **a pneumatic drive assembly (68)** to provide a simple and compact drive system, and a safety mechanism to prevent from accidentally firing of the tool (page 6, [0102]).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al. apparatus by incorporating the pneumatic drive assembly for a more compact and simple drive system and the safety mechanism as taught by Green et al..

Response to Arguments

6. Applicant's arguments with respect to claims 1, 2 and 5-9 have been considered but are moot in view of the new ground(s) of rejection.

7. However, in response to the Applicant's argument that:

"It is respectfully submitted that Mizzy does not cure the above deficiency. Claim 1, as amended, recites "a pressure sensitive trigger which regulates the advancement of said roll nut along said lead screw which, in turn, *regulates the speed at which said surgical fasteners are deformed.*" In contrast, Mizzy discloses "a pressure sensitive triggering mechanism for initiating the *administration of a dose responsive to a pre-determined pressure being exerted by the apparatus against the subject.*" (Col. 2, lines 29-32). (Emphasis added). Thus, the mechanism of Mizzy varies the pressure required to initiate a dosage of medicament rather than a pressure sensitive trigger that varies the speed of deformation of a staple based on the amount of pressure on the trigger. Moreover, Mizzy teaches that pressure may be varied for a triggering event (e.g., inoculation of "a young chick" or inoculation of "a horse" by adjusting the triggering mechanism (Col. 8, lines 24-33)), not varied to control the speed of

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deformation of staples or any other parameters or characteristics of the prior art device. An exhaustive search of the specification of Mizzy does not yield any teaching or suggestion of this novel feature. Moreover, varying the speed of a dose of medicament is counter intuitive since this would directly result in prolonged discomfort/pain on a patient/subject level. Thus, Mizzy clearly teaches away from controlling the speed of deforming staples.”,

this is not found persuasive for the following reasons:

Mizzy et al. is relied upon for the teaching of a “pressure sensitive trigger”, a trigger that actuates and regulates the pressure of a pneumatic instrument. It is maintained that Mizzy et al. “pressure sensitive trigger” responses to the triggering action and in turn regulates the pressure of an pneumatic instrument.

Applicant’s disclosure stated that: “trigger 580 cooperates with trigger valve 590 to regulate the pneumatic pressure to the pneumatic drive assembly 520” (page 17, lines 21 to page 18, lines 1) and “pressure sensitive trigger 580 is utilized to activate the pneumatic drive assembly 520” (page 18, lines 7-8).

Accordingly, it is believed that Mizzy et al. discloses the “pressure sensitive trigger” as recited in claim 1:

Furthermore, it should be pointed out that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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Conclusion

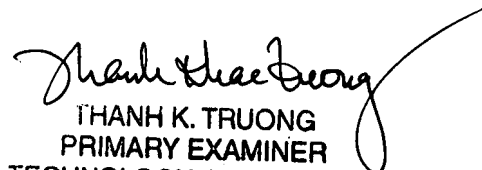
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thanh K. Truong whose telephone number is 571-272-4472. The examiner can normally be reached on Mon-Thru 8:00AM - 6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tk
August 31, 2007.


THANH K. TRUONG
PRIMARY EXAMINER
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